TOMTEC IMAGING SYSTEMS

K110667

February 10th, 2011

# Traditional 510(k) Summary

APR - 8 2011

Image-Arena and Image-Arena Applications
Image-Arena 4.5
Echo-Com 4.5
Image-Com 4.5

**Additional Marketing Name:** IQ Workstation

**Owner's Name and Address**

TomTec Imaging Systems GmbH
Edisonstrasse 6
D-85716 Unterschleissheim

**Contact Person**

Inge Scheidt
QM & RA Officer
Phone ++49-89-32175-515
Fax ++49-89-32175-750

**Common, Classification & Proprietary Names**

| | |
|---|---|
| Common Name: | Various Image Analysis System Software |
| Classification Name: | Picture archiving and communications system |
| Proprietary Name(s): | Image-Arena and Image-Arena Applications<br>Image-Arena 4.5<br>Image-Com 4.5<br>Echo-Com 4.5 |

## Predicate Devices

| | | |
|---|---|---|
| Predicate Device 1 | K083348 | Image-Arena Platform 4.0, Server Manager 4.0, Echo-Com 4.0,Image-Com 4.0, TomTec Imaging Systems GmbH |
| Predicate Device 2 | K061995 | Xcelera, Philips Medical Systems North America CO. |

## Device Description

**Image-Arena** is an SQL database based image management system that provides the capability to import, export, store, retrieve and report digital studies.

**Image Arena** is developed as a common interface platform for TomTec - and commercially available analysis and quantification tools (= clinical application packages) that can be connected to Image-Arena through the Generic Clinical Application Package interface (= Generic CAP Interface)

**Image-Arena** manages different digital medical data from different modalities except digital mammography.

**Image-Arena** is suited as stand-alone workstation as well as networked multi-system server / client installations.

Image-Arena runs on an integrated Intel Pentium high performance computer system based on Microsoft™ Windows standards. Communication and data exchange are done using standard TCP/IP, DICOM and HL7 protocols.

Image-Arena provides the possibility to create user defined medical reports.

The system does not produce any original medical images.

**Image-Com** is a clinical application package software for reviewing and measuring of digital medical data. Image-Com is either embedded in Image-Arena platform or can be integrated into Third Party platforms, such as PACS or CVIS.

**Echo-Com** is a clinical application package software for reviewing and reporting of digital stress echo data. Echo-Com is either embedded in Image-Arena Platform or can be integrated into Third Party platforms, such as PACS or CVIS.

## Indications for use and Intended use

The Image-Arena software platform is intended to import, export, store, retrieve and report digital studies. The Image-Arena software is based on a SQL - database and is intended as an image management system. The Image-Arena software can import certain digital 2D or 3D image file formats of different modalities.

Image-Arena offers a Generic Clinical Application Package interface in order to connect TomTec applications as well as commercially available analysis and quantification tools to the Image-Arena platform.

The software is suited for stand-alone workstations as well as for networked multi-system installations and therefore is an image management system for physician practices and hospitals. It is intended as a general purpose digital medical image processing tool.

Image-Arena is not intended to be used for reading of mammography images.

Image-Com software is intended for reviewing and measuring of digital medical data of different modalities. It can be driven by Image-Arena or other third party platforms and is intended to launch other commercially available analysis and quantification tools.

Echo-Com software is intended to serve as a versatile solution for Stress echo examinations in patients who may not be receiving enough oxygen because of blocked arteries. Echo-Com software is intended for reviewing, wall motion scoring and reporting of stress echo studies.

## Technological Characteristics Comparison

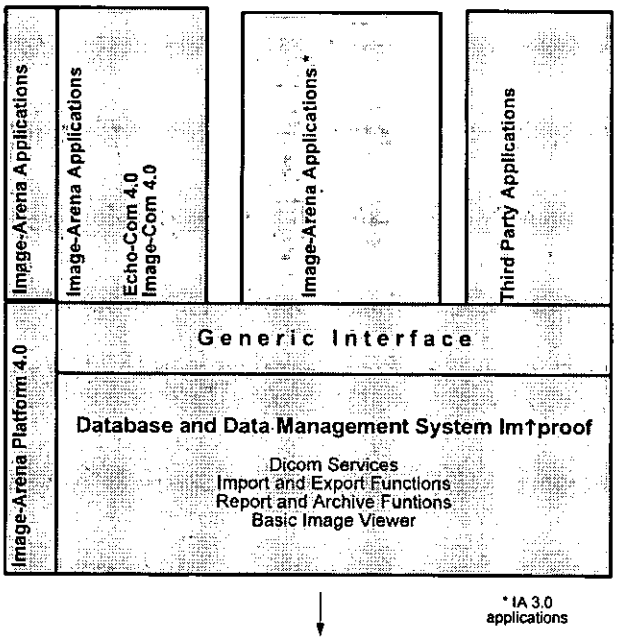
The proposed and the predicate devices are software devices that run on high performance computer system to receive, store, display and digital process of medical images.

The Image-Arena Application software tool package is modular structured and consists of different software modules, combining the advantages of the previously FDA cleared software products:

| | | |
|---|---|---|
| Predicate Device 1 | K083348 | Image-Arena Platform 4.0, Server Manager 4.0, Echo-Com 4.0,Image-Com 4.0, TomTec Imaging Systems GmbH |
| Predicate Device 2 | K061995 | Xcelera, Philips Medical Systems North America CO. |

**Predicate Devices:**

**TomTec Image-Arena and Image-Arena Applications**




**Predicate Devices:**

K083348

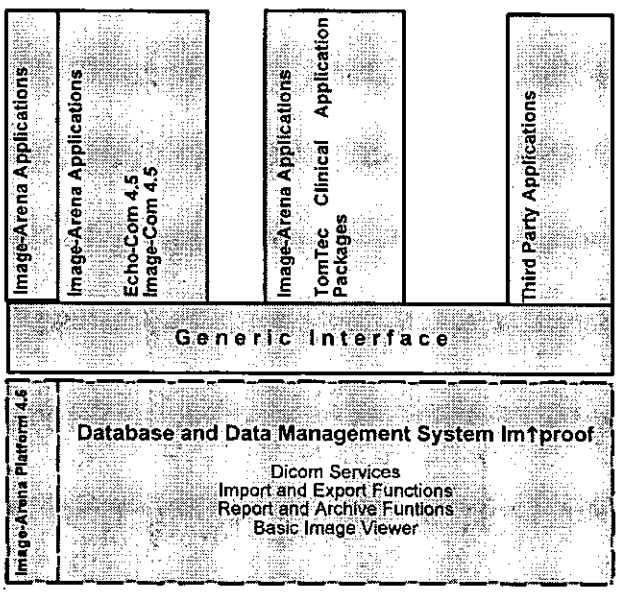
TomTec Image-Arena Platfrom 4.0, Server Manager 4.0, EchoCom 4.0, Image-Com 4.0

K061995

Xcelera

**New Device:**

**TomTec Image-Arena 4.5 and Image-Arena Applications**




**New Device:**

TomTec Image-Arena 4.5 and Image-Arena Applications

**Discussion according non-clinical performance data testing**

Testing was performed according to internal company procedures. Software testing and validation were done at the module and system level according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release.

**Discussion according clinical performance data testing**

The overall product concept was clinically accepted and the clinical test results support the conclusion that the device is as safe as effective, and performs as well as or better than the predicate device.

**Test Conclusions of non-clinical and clinical performance data**

Test results support the conclusion, that the device is as safe as effective, and performs as well as or better than the predicate device.

Munich, February 10th, 2011

J. Scheidt

Inge Scheidt
QM & RA Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Inge Scheidt
QM & RA Officer
TomTec Imaging Systems GmbH
Edisonstrasse 6
Unterschleissheim, Bavaria, D-85716
GERMANY

APR - 8 2011

Re: K110667
Trade/Device Name: Imag-Arena Image.Arena Applications: Image-Arena 4.5; Echo-Com 4.5; Image-Com 4.5
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 10, 2011
Received: March 9, 2011

Dear Mr. Scheidt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K110667

Device Name:

**Image-Arena and Image-.Arena Applications**
**Image-Arena 4.5**
**Echo-Com 4.5**
**Image-Com 4.5**

**Additional Marketing Name: IQ Workstation**

**Indications for Use:**

The Image-Arena software platform is intended to import, export, store; retrieve and report digital studies. The Image-Arena software is based on a SQL - database and is intended as an image management system. The Image-Arena software can import certain digital 2D or 3D image file formats of different modalities.

Image-Arena offers a Generic Clinical Application Package interface in order to connect TomTec applications as well as commercially available analysis and quantification tools to the Image-Arena platform.

The software is suited for stand-alone workstations as well as for networked multi-system installations and therefore is an image management system for physician practices and hospitals. It is intended as a general purpose digital medical image processing tool.

Image-Arena is not intended to be used for reading of mammography images.

Image-Com software is intended for reviewing and measuring of digital medical data of different modalities. It can be driven by Image-Arena or other third party platforms and is intended to launch other commercially available analysis and quantification tools.

Echo-Com software is intended to serve as a versatile solution for Stress echo examinations in patients who may not be receiving enough oxygen because of blocked arteries. Echo-Com software is intended for reviewing, wall motion scoring and reporting of stress echo studies.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510k K110667